

D2A

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
22 July 2004 (22.07.2004)

PCT

(10) International Publication Number  
**WO 2004/060225 A1**

(51) International Patent Classification<sup>7</sup>: **A61F 13/00**

(21) International Application Number:  
PCT/US2003/037075

(22) International Filing Date: 3 December 2003 (03.12.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/437,146 31 December 2002 (31.12.2002) US  
60/482,775 27 June 2003 (27.06.2003) US  
60/503,546 17 September 2003 (17.09.2003) US  
60/518,317 10 November 2003 (10.11.2003) US

(71) Applicants: **OSSUR HF [IS/IS]**; Grjothals 5, IS-110 Reykjavik (IS). **OSSUR NORTH AMERICA, INC.** [US/US]; 27412 Laguna Hills Drive, Aliso Viejo, CA 92656 (US).

(72) Inventors: **SIGURJONSSON, Gudmundur, Fertram;** Bergstadastraeti 62, IS-101 Reykjavik (IS). **ELEFSEN, Thordur, M.;** Klapparhlid 30, Suite 304, IS-270 Mosfellsbaer (IS).

(74) Agents: **CASELL, Justin, J. et al.;** Bacon & Thomas, PLLC, 625 Slaters Lane - 4th Floor, Alexandria, VA 22314 (US).

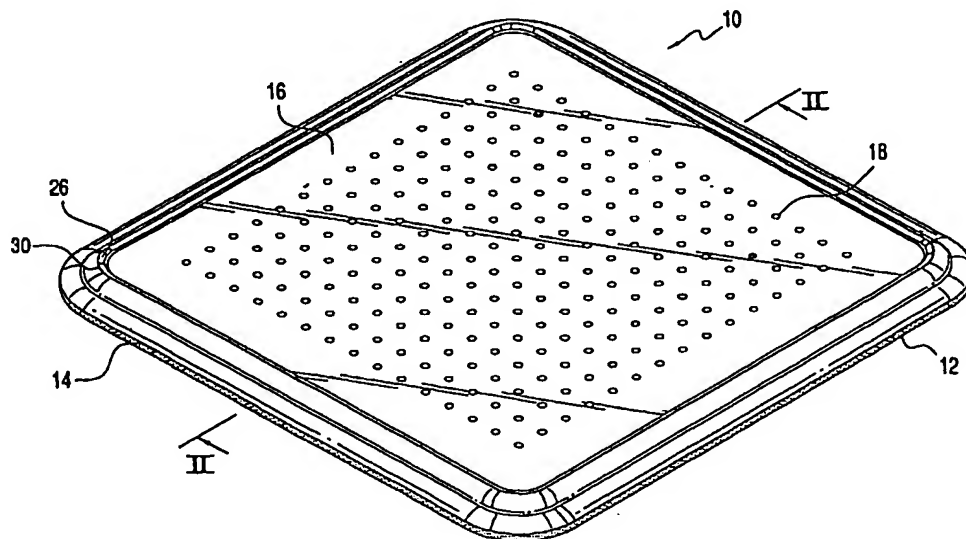
(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:  
— with international search report

[Continued on next page]

(54) Title: **WOUND DRESSING**



(57) Abstract: A wound dressing including an absorbent core and a backing layer connected thereto. The backing layer defines at least one compliant element disassociated from the distal surface of the absorbent core. The compliant element includes at least one ridge extending outwardly relative to the distal surface of the absorbent core. A method for making the compliant element and connecting the backing layer to the absorbent core includes using a platen in communication with a vacuum and compressed air.

WO 2004/060225 A1

**WO 2004/060225 A1**

---



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## WOUND DRESSING

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to a wound dressing, and more particularly to a wound dressing having a construction with improved skin adherence and absorptive capabilities, and methods for producing the same.

#### 2. Discussion of Related Art

Historically, many diverse materials of various origins have been used to treat wounds by absorbing wound fluids and tissue, hereinafter generally referred to as exudate, from a wound site with some type of absorbent material.

In recent years, use of polymeric-based wound care products have become increasingly popular to control wound site environmental factors such as water vapor, oxygen permeability, bacterial impermeability, and absorption of exudate. Such wound care products are tailored to meet specific requirements including conformability to a body portion, selective adherence to a wound bed, and adhesiveness to the skin surrounding the wound site.

Recently, occlusive or moisture-retentive dressings have gained increasing acceptance in treating wounds, in particular pressure sores and ulcers. A wide variety of types of structures are known in the art for use in or as occlusive dressings and generally comprise components for receiving, absorbing and retaining exudate. Typically, these wound care products include polymeric foams, polymeric films, particulate and fibrous polymers, hydrogels and hydrocolloids. Dressings with at least one of these components promote wound healing by providing a moist environment, while removing excess exudate and toxic components, and further serve as a barrier to protect the wound from secondary bacterial infection. While these known occlusive wound dressings can effectively manage a wound, many have been found to possess certain limitations or disadvantages.

In wound care, one of the main objectives of a wound dressing is to increase, improve or maximize utilization of the absorbent capacity of the dressing so as to reduce or eliminate maceration, and facilitate the healing process of the wound. The control of exudate is of prime importance if a moist wound microenvironment is to be maintained. Unfortunately, many wound dressings have been found to remove all the exudate that a wound produces, thereby causing a "dry" wound that is undesirable in the wound healing process or in the alternative, such wound dressings have been found to absorb or control the exudate insufficiently, thereby leading to a pooling of the exudate which may increase the risk of bacterial proliferation and lead to infection.

Many wound dressings in the prior art include an absorbent layer having absorptive capabilities. Typically, the absorbent layer contains hydrophilic materials that absorb exudate and permit the wound dressing to be left in place for a period of days. Such absorbent layers may comprise a non-woven material or foam containing hydrocolloid particles such as the dressings described in U.S. Patents 4,373,519 and 6,566,576, or a hydrophilic foam layer, such as in the dressings described in U.S. Patents 5,409,472, 5,782,787, 6,040,492, 6,051,747, and 6,486,378.

While absorbent layer dressings are configured to absorb wound exudate, they often possess the disadvantage of being limited in the amount of exudate that may be absorbed. The limit to the maximum absorption of absorbent foam is often directly related to their geometrical size prior to absorbing a fluid. For example, hydrophilic foams may expand only to 12-15% of their original size. Another disadvantage is that it has been found that a certain amount of the exudate can be "squeezed" out of absorbent foam dressings due to poor liquid retention. The ability of exudates to be squeezed from the foam layer, and thus dressing itself, poses a risk of infection and may interfere with the healing of the wound.

Yet another disadvantage with known dressings is that absorption of exudate by an absorptive layer in contact with the wound causes the central portion of the applied dressing to swell and push up against the wound.

Continued swelling can induce separation of the skin adherent layer from the skin outside the wound area, especially at the border of the wound dressing whereat a "curling" effect may occur. This excessive swelling of the wound dressing may further lead to leakage of the exudate from the periphery of the dressing, thereby providing a tract for the invasion of pathogenic microorganisms and further promoting maceration of the wound site.

Conventionally, a backing layer is provided that comprises a liquid impervious film that is attached to the absorbent layer to prevent exudate from seeping from the dressing. A difficulty arises during fluid uptake in that as the absorbent core expands, the backing layer must accommodate the expansion of the absorbent layer without causing curling of the dressing. An attempted solution to this problem is described in U.S. Patent 4,738,257 which discloses a backing layer formed of a thin elastic sheet which is yieldable as the absorbent core swells. It has been found, however, that a liquid impervious plastic film cannot be made to sufficiently stretch in keeping with the expansion of the absorbent layer, and as a result, the film counteracting with the swelling absorbent layer may produce the aforesaid curling at the border of the dressing. Another proposed solution is provided in U.S. Patent 6,040,492 which discloses a wound dressing that includes a backing layer that is attached to an absorbent foam core and includes a plurality of wrinkles that substantially flatten as the foam core swells. While the backing layer may accommodate the expansion of the foam core, the fluid uptake of this wound dressing is limited by the expandability of the foam core itself. Accordingly, due to the limited absorptive capacity of the foam core, the dressing must be replaced often.

Ideally, a wound dressing must be adhesive in nature such that it may attach to the wound site while being non-toxic and eliciting no more than a minimal allergenic response. Moreover, a wound dressing should possess the ability to prevent bacteria from entering the wound from the ambient environment while providing a suitable moisture transmission rate.

It has been found, however, that many known occlusive dressings possess the disadvantage of relying solely on a pressure sensitive adhesive layer that is used to secure the dressing to skin, for instance an acrylate glue

having a high specific adhesiveness. Typically, a wound dressing with only an adhesive has a tendency to strip the central portion of the dressing from the wound when removed from the wound and thus may damage healing tissue.

Wound dressing have been commercially available that include an absorbent foam core with a wound contacting surface coated with a layer of silicone gel. The silicone gel randomly lines portions of the walls of the pores of the absorbent foam to form a plurality of randomly formed apertures. These apertures are formed by capillary action when an uncured silicone gel is applied to the foam core. One drawback to this approach is that the silicone gel may close some of the pores, and another drawback is that the holes are randomly formed which may lead to localized areas that inhibit the uptake of the exudate into the foam core. While in some applications it may be desirable to provide the wound dressing with a greater concentration of apertures at selected regions of the wound dressing to increase exudate uptake at such areas, this approach does not accommodate such a formation of a predetermined pattern of apertures. Furthermore, another drawback to this approach is that the surface roughness of the silicone layer is largely dependent upon the surface of the foam to be coated, and in the event it is desired to obtain a smooth silicone layer to be worn on the skin, this approach fails to yield such a smooth silicone layer.

Developments in the field of silicone manufacturing have led Ossur hf of Reykavik, Iceland, and assignee of the present invention, to produce silicone products adapted for skin contact that provide superb softness, gentle skin contact, and may include unique skin care ingredients. In particular, such silicone manufacturing has led to advances in improved comfort and cushioning of prosthetic suspension liners that have excellent durability and intimacy using proprietary silicone technology of Ossur hf. It has been found that by applying the silicone technology of Ossur hf to produce an ultra-thin, perforated tacky silicone sheet, a silicone adhesive layer can be produced that possesses superior gentle adherence to wound sites while not damaging skin and the wound bed due to single or repeated removal of the silicone layer.

Despite the availability of a variety of absorbent wound dressings, there is a need and a demand for an improved wound dressing which prevents wound trauma upon wound dressing changes, improves the durability and lifetime of the wound dressing, anatomically conforms to a wound and possesses improved fluid uptake, retention and removal properties. Most importantly, it is desired to produce a wound dressing having an adhesive layer that does not possess the drawbacks of known adhesive layers, and instead, gently adheres and detaches from a wound site while providing superior fluid uptake. Moreover, there is a need and a demand for an improved method of forming such an improved wound dressing that is both simple and cost effective.

#### SUMMARY OF THE INVENTION

The present invention is directed to an improved wound dressing possessing superior absorbent capabilities including increased fluid uptake and enhanced retention properties. In an embodiment of the invention, a wound dressing includes an absorbent core defining opposed proximal and distal surfaces. The distal surface of the absorbent core defines a central portion, a border portion and an intermediate portion interposed between the central and border portions. A liquid impervious, vapor permeable backing layer is connected to the distal surface of the absorbent core and includes at least one compliant element disassociated from the distal surface of the absorbent core.

In another embodiment of the invention, the compliant element includes a ridge concentric with the periphery of the absorbent core. The ridge of the compliant element is configured to extend outwardly relative to the distal surface of the absorbent core, even if the wound dressing has absorbed a maximum amount of moisture content. In yet another embodiment of the invention, the compliant element includes two ridges defining inner and outer boundaries of the compliant element. Both of the ridges are configured to remain extending outwardly relative to the distal surface of the absorbent core despite the level of absorption of the wound dressing.

The incorporation of the compliant element in the backing layer permits enhanced accommodation of the expansion of the wound dressing. In an embodiment of the invention, the absorbent core contains discrete portions of a moisture absorbent material. In this embodiment, the compliant element is generally positioned near the peripheral border of the wound dressing and effectively functions as a joint to permit migration of the discrete portions of absorbent material from the absorbent core. When the absorbent core and the absorbent material have absorbed a quantity of moisture, an expandable reservoir is defined between central portions of the backing layer and the absorbent core. This reservoir is formed when the discrete portions of absorbent material have absorbed a quantity of exudate and results from detachment of the central portion of the backing layer from the central portion of the absorbent core due to the swelling and expansion of such absorbent material.

A method of the invention is provided for making an embodiment of a wound dressing of the invention including an absorbent core having proximal and distal surfaces, and a liquid impervious, vapor permeable backing layer connected to the absorbent core. The backing layer has a portion defining a compliant element disassociated and outwardly extending from the distal surface of the absorbent core. The method includes the steps of securing a border portion of the backing layer to a border portion of the absorbent core located near the periphery thereof, connecting a central portion of the backing layer to a central portion of the absorbent core, and forming the compliant element by drawing the compliant element away from the absorbent core.

A method of the invention employs a platen configured with a predetermined profile corresponding to the compliant element and the border and central portions of the backing layer. The platen is used to secure the backing layer to the absorbent core and includes a groove defining the form of the compliant element of the backing layer selectively in communication with a vacuum.



The platen is configured to draw the backing layer against the platen prior to connecting the border and central portions thereof to the absorbent core by pulling the area of the backing layer corresponding to the compliant element into the groove with a vacuum in communication therewith. The platen is applied with the backing layer carried thereon against the absorbent core. The platen is heated at a suitable temperature to secure the border portion of the backing layer to the absorbent core. The platen is then removed from the backing layer by relieving the vacuum from the backing layer after the border portion of the backing layer is secured to the absorbent core.

Numerous other advantages and features of the present invention will become more readily apparent from the following detailed description of the invention, the accompanying examples, drawings and the appended claims.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an embodiment of a wound dressing of the invention;

FIG. 2 is a sectional view of the wound dressing along line II-II in FIG. 1;

FIG. 3 is a perspective view of an embodiment of a wound dressing of the invention;

FIG. 4 is a plan view showing an embodiment of a facing layer of the invention;

FIG. 5 is an enlarged view of a section of another embodiment of the wound dressing in FIG. 2;

FIGS. 6-8 are sectional views illustrating progressive swelling of the wound dressing in FIGS. 1-2 over a wound site;

FIG. 9 is an enlarged view of a section of the wound dressing in FIG. 8;

FIG. 10 is a plan view showing an embodiment of a facing layer of the invention;

FIG. 11 is a plan view showing an embodiment of receptacles of an absorbent core of the invention;

FIG. 12 is a plan view showing an embodiment of a facing layer of the invention;

FIG. 13 is an elevational view showing another embodiment of receptacles and a facing layer of the invention;

FIG. 14 is a cross-sectional view showing an embodiment of a platen used to apply a backing layer to an absorbent core of the invention; and

FIGS. 15-19 are schematic views showing an arrangement for applying a backing layer to an absorbent core of the invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIGS. 1 and 2, the wound dressing 10 of the present invention preferably includes a perforated hydrophobic, skin adherent facing layer 12, an absorbent core 14, and a liquid impervious, moisture permeable backing layer 16. The wound dressing depicted in FIG. 1 is in a dry state substantially devoid of moisture. As more fully exemplified in FIG. 2, the absorbent core 14 defines a proximal surface  $p$  that is intended to face towards a wound surface  $w$  and a distal surface  $d$  that is opposed to the proximal surface  $p$  and faces away from a wound surface. In a basic configuration, the dressing 10 comprises the facing layer 12 secured to the proximal surface  $p$  of the absorbent core 14 and the backing layer 16 attached and sealed to at least part of the distal surface  $d$  of the absorbent core 14.

In a preferred embodiment, the absorbent core 14 defines a plurality of receptacles 18 arranged in a predetermined pattern wherein the receptacles 18 are defined as a repeating series of cylindrical compartments. As shown in FIG. 2, the receptacles 18 open at the distal surface  $d$  of the absorbent core 14

and extend a distance into the absorbent core 14 a distance  $t_1$ , short of its entire thickness  $t$ . The receptacles may assume a variety of configurations and may be cylindrical in shape, extend transversely along at least a portion of the distal surface of the absorbent core, or assume other possible configurations as will be discussed below. The plurality of receptacles 18 contain discrete portions of absorbent material 20 that absorb exudate from the wound and migrate from the receptacles 18 towards the backing layer 16 upon absorption of such exudate.

As illustrated in FIG. 2, the absorbent core 14 generally defines central, intermediate and border portions 22, 23, 24. Preferably, the backing layer 16 is secured to the border portion 24 of the absorbent core 14 and sealed along its periphery. The border portion 24 preferably includes a bevel 28 defined near or along a peripheral edge thereof and is provided to retain any loose absorbent material 20 from the receptacles 18 within the dressing 10. As will be discussed more fully below, the backing layer 16 is preferably lightly adhered to the central portion 22 of the absorbent core 14 when the dressing 10 is in a dry state.

The backing layer 16 of the dressing 10 preferably includes a compliant element 26 that is interposed between the central and border portions 22, 24 of the absorbent core 14. The compliant element 26 is generally concentric with the central portion 22 and comprises a portion of the backing layer 16 that may not be adhered to the absorbent core 14 when the dressing 10 is in a dry state. Preferably, the compliant element 26 includes at least one concentric ridge. While FIG. 2 shows the dressing 10 with a compliant element 26 having only one concentric ridge 30. FIG. 3 illustrates a dressing 10 having a plurality of ridges wherein inner and outer ridges 31, 32 extend outwardly from the distal surface  $d$  of the absorbent core 14, and generally constitute inner and outer boundaries of the compliant element 26.

It will be understood that the compliant element may assume a variety of configurations. For example, the orientation of the compliant element may be

arranged in a variety of directions such as the ridge extending in a range of directions from being generally parallel to the absorbent core on the border portion side of the compliant element to being generally parallel to the absorbent core on the central portion side of the compliant element.

As shown schematically in FIG. 5, the compliant element 26 is not limited to being positioned generally along the intermediate portion of the absorbent core. The compliant element 26 may be positioned on the border or the central portions of the wound dressing wherein the compliant element 26 may include at least one ridge 30 or segment thereof on at least one of the border or central portions of the wound dressing. Such adaptation of the wound dressing to include a compliant element on at least one of the border or central portions of the wound dressing may be provided to improve the expandability and distension of the backing layer relative to the distal surface of the absorbent core.

The facing layer 12 is preferably secured to the proximal surface *p* of the absorbent core 14. The facing layer 12 includes a plurality of apertures 34 that are preformed in a pattern prior to securing the facing layer 12 to the absorbent core 14. As shown schematically in FIGS. 2 and 4, the plurality of apertures 34 may be arranged in a predetermined pattern. The plurality of apertures 34 may be configured to correspond to regions near or at the plurality of receptacles 18 of the absorbent core 14 so as to transport exudate from a wound site to the absorbent core 14. The facing layer 12 is preferably secured only to the proximal surface *p* of the absorbent core 14 and preferably does not coat the walls of the pores or holes of the absorbent core 14 defined near the proximal surface *p* thereof. It will be understood, however, that portions of the facing layer may fill irregularities disposed along the proximal surface of the absorbent core or pores of the absorbent core so as to improve the security of the facing layer to the absorbent core.

While not wishing to be bound by a particular mechanism of operation, the present invention is intended to function as a dressing 10 in the manner

depicted in FIGS. 6 to 8, after application of the dressing to a fluid-exuding skin wound. It will be understood that in the context of the invention, the terms fluid, moisture and exudate are used interchangeably regarding wounds and wound dressings. The dressing 10 is placed onto a wound site *w* with the facing layer 12 directed over the wound bed *b*. The facing layer 12 may adhere to the intact skin around the wound site *w* as well as to the wound bed *b*. The dressing 10 is maintained in close apposition to the wound bed *b* in part by the capillary action of the exudate entering the absorbent core 14 and by the facing layer 12.

As illustrated in FIG. 6, fluid exuded by the wound bed *b* will be drawn through the apertures 34 towards the absorbent core 14, and the absorbent material 20 contained in the receptacles 18. After being applied over the wound site *w* for an extended period of time, the applied dressing 10 may appear as shown in FIG. 7 with a slightly enlarged domed, reservoir configuration 36 extending over the central portion of the absorbent core 14. The reservoir 36 is caused by the absorbent material 20 that has absorbed a desired quantity of exudate from the receptacles 18 and discrete portions thereof have swelled and migrated from the receptacles, thereby causing distension of the backing layer 16. The swollen exudate-laden discrete portions of absorbent material 20 cause the backing layer 16 to detach from the distal surface *d* of the absorbent core 14 in a predictable manner and to distend upwardly to further permit continued absorbing and swelling of the dressing 10 over the wound site *w*. In addition, the absorbent core 14 will expand or swell both transversely and longitudinally, and the area of absorbent core 14 will generally increase with increased fluid absorption.

While the backing layer 16 remains sealed along the border portion of the dressing 10, the reservoir 36 is formed such that it is defined between the backing layer 16 and the distal surface *d* of the absorbent core 14, and sealed along the border portion 24. The reservoir 36 permits the migration of the swollen discrete portions of absorbent material 20 from the receptacles 18 and greatly expands the retention of fluid from the wound bed *b*. The compliant

element 26 effectively functions as a flexible joint for the backing layer 16 by permitting additional expansion of the backing layer 16 in providing additional flexibility and expansion of the backing layer 16 due to the swelling of the absorbent material 20. As shown in FIG. 8, the dressing 10 has nearly reached its swelling capacity and the backing layer 16 has distended to its maximum. Most notably, at this advance stage of swelling, the border portion 24 of the dressing 10 remains attached to the wound site *w* due to the provision of the compliant element 26 which compensates for the expansion and swelling of the absorbent core 14 and the absorbent material 20, and the distension of the backing layer 16. It will be further noted that the ridge 30 generally does not fully flatten relative to adjacent portions of the backing layer 16 and generally extends outwardly, at least in part, from the distal surface *d* of the absorbent core 14 and in relation to the distended portion of the backing layer 16 delimited by the compliant element 26.

It will be understood that the preferred facing layer 12 also has suitable elastic properties to enable it to stretch as the absorbent core 14 expands laterally.

When the dressing 10 has expanded to a maximum capacity, defined as an exudate-laden or fully saturated dressing, it will be desirable to remove and replace the dressing 10. When in a saturated or fully exudate-laden stage, the corners along the border portion 24 of the dressing 10 generally remain adhered to the wound site *w* despite the excessive uptake of exudate, as exemplified in FIG. 9, since the facing layer 12 provides sufficient adherence to the skin surrounding the wound site *w*. By observing the extent of swelling of the dressing in relation to the degree of fluid uptake into the absorbent core and by the absorbent material, one can be visually determine when it is appropriate to remove the dressing.

As exemplified in FIG. 10, the dressing 10 may include an additional adhesive 19 disposed on the facing layer 12. Preferably, the adhesive 19 is deposited on the facing layer 12 at or near a portion corresponding to the

border portion of the absorbent core 14. The pressure sensitive adhesive 19 is preferably a tacky pressure sensitive silicone or an acrylate adhesive known in the art of wound dressings.

In a preferred embodiment, the absorbent core 14 comprises preferably a hydrophilic synthetic polymer conformable to body surfaces and adapted to be capable of absorbing fluid. It is desirable that the absorbent core absorb exudate rapidly so as to enhance its effectiveness in the dressing of the invention, and in particular, the fluid uptake to the receptacles containing the absorbent material. In addition to absorption, an effective wicking mechanism is desirable, that is the absorbent core should rapidly direct fluids away from the proximal surface of the absorbent core to more remote areas for storage (i.e., the receptacles containing the discrete portions of absorbent material), so as to minimize local saturation and maximize the efficiency of the absorbent core.

A preferable absorbent core is constructed of flexible open-cell foam that is at least slightly hydrophilic. Suitable foams have an open cell size of 30 to 700 microns, and preferably a cell size of 50 to 300 microns. The open cells permit transport of fluid and cellular debris into and within the foam, and it is preferred that the cell size of areas of the foam be of sufficient size to encourage capillary action and promote fluid transport.

The absorbent core may expand about 135% of its size when saturated with fluid. When combined with the facing and backing layer of the invention, the absorbent core may expand to only about 110% of its dry size when exudate laden.

In accordance with one embodiment of the invention, the absorbent foam comprises a gradient of cell sizes across the thickness of the absorbent core such that the cell size decreases in the direction of the distal surface and of the absorbent core. Since the cell sizes are greater at and near the proximal surface of the absorbent core, the capillary forces are stronger and therefore will drain fluid near the proximal surface of the absorbent core and draw the fluid towards the receptacles. In addition, the absorbent foam may include a

cell size gradient that is directed towards the receptacles, thereby providing localized regions in the absorbent foam that are configured to have increased capillary forces directed towards the receptacles to aid in the guidance of fluid thereto.

The foam may be made, for example, from polyurethane, cellulose, carboxylated butadiene-styrene rubber, polyester foams, hydrophilic epoxy foams or polyacrylate. In a preferred embodiment, the foam is formed from hydrophilic polyurethane foam, such as polyurethane foam made by Reynel Inc. (Boothbay, ME) under product designation L00562-B. Since the aforesaid foams are hydrophilic per se and further in view of the use of the receptacles containing absorbent material, it is not necessary to treat the foams to render them more hydrophilic in a preferred embodiment.

In another embodiment, if desired, the foam may be treated so as to be more hydrophilic and therefore increase the tendency of the exudate to coagulate more rapidly in the foam, yet only to the extent that the foam is not too hydrophilic so that the hydrophilic properties of the foam prevents transport of the exudate to the absorbent material. In such an embodiment, the level of hydrophilic properties of the absorbent foam may be designed such that the surface tension is minimized to allow the easy passage of fluid into foam cells. The fluid is thus retained in the absorbent foam while maintaining a high relative humidity at the wound site.

It will be understood that the absorbent core is not limited to being constituted of foam. In another embodiment, the absorbent core may be a porous woven or non-woven material that may be produced by any number of means using known materials available to those skilled in the art. For example, the absorbent core may exist as a bulky, loosely formed web composed of very short cellulose fibers arranged in a random or non-random array, a pad of cellulose flakes, or a polymeric fibril matrix.

The thickness of the absorbent core will range from 0.5 mm to 20 mm, and is preferably between 3mm to 5mm.



The absorbent core may include an array of receptacles formed therein and may be defined in any suitable preselected pattern that can contain a desired bulk or quantity of discrete portions absorbent material, while maintaining sufficient strength and flexibility suitable for a dressing of the invention. In a preferred embodiment shown in FIG. 1, the pattern of the receptacles 18 is in a grid-like configuration. Preferably, such receptacles have a uniform, predetermined shape and size, and extend across the distal surface *d* of the absorbent core. In this embodiment, the receptacles are positioned in a rectangular pattern, and the receptacles are generally spaced apart 5 mm (measured from the center axis of each receptacle). The depth of each receptacle is generally 4-5 mm, and positioned at least 0.5 mm from the facing layer. In this embodiment, the pattern may be tailored to include more receptacles at specific regions of the dressing as opposed to other regions.

In an embodiment of the wound dressing shown in FIG. 11, there is a higher density of receptacles 18 at the central portion 22 of the absorbent core 14 than near the border portion 24 of the dressing 10. The amount of receptacles at any given region of the absorbent core may be dependent upon the perceived areas of a greater amount of local occurrence of fluid, such as at the central portion, to maximize fluid absorption, and further limit the absorption of fluid at certain areas of the absorbent core such as at the border portion.

As shown in FIG. 2, the receptacles 18 are arranged to open at the distal surface of the absorbent core 14 and extend a distance into the entire thickness thereof. In a preferred embodiment, the receptacles extend a distance  $t_1$ , short of the entire thickness  $t$  of the absorbent core 18, and it is preferred that the receptacles extend a distance 70-90% of the total thickness of the absorbent core 14. It will be understood, however, that in an embodiment of the wound dressing, the receptacles may extend through the entire thickness of the absorbent core.

In another embodiment of the wound dressing, the receptacles 18 may be arranged, as shown in FIG. 13, to extend at different distances into the thickness of the absorbent core 14 on the basis of their location and the local occurrence of fluid exuded from a wound site. In this embodiment, the receptacles 18 located closer to the center of the dressing 10 extend deeper into the thickness of the absorbent core 14 whereas the receptacles 18 closer to the border 24 of the absorbent core extend a shallower distance into the thickness of the absorbent core 14 than the receptacles 18 at the central portion 22. It follows that the deeper receptacles 18 will contain more absorbent material 20 than the shallower receptacles 18, and therefore provide a greater localized region of absorption.

Since the receptacles preferably extend only partly into the total thickness of the absorbent core, exudate will be transported to and absorbed by the absorbent material. This effect leaves the proximal side of the absorbent core without the receptacles in a desirably moist environment without excessive saturation of exudate and thus permits the dressing to remain on the wound site for a longer period of time.

In a preferred embodiment shown in FIGS. 1 and 2, the shape of the individual receptacles 18 is uniform and generally cylindrical. The shape of the receptacles is at least partly chosen to maximize the containment of the discrete portions of absorbent material and to facilitate the migration thereof when swollen by fluid. The receptacles are not limited to a cylindrical configuration; the receptacles may take on the shape of pyramids, channels, hemispheres, cones, blocks and truncated variations and combinations thereof. Moreover, the receptacles may include a taper extending from their opening to their base portion so that the receptacles have a greater width near the opening than at the base portion. This configuration facilitates migration of swollen, moisture-laden discrete portions of absorbent material from the receptacles so that they can flow more freely from the receptacles. Alternatively, the

receptacles may be arranged in a random pattern along a transverse direction of the distal surface of the dressing.

In an embodiment of the absorbent core, the receptacles may comprise a plurality of channels extending transversely along at least a portion of the distal side of the absorbent core. In this embodiment, the channels may have a denticulate or an undulating cross-sectional profile. This embodiment may be useful in a wound dressing wherein the absorbent core is too thin to include receptacles having a form such as the aforesaid cylindrical receptacles.

The size of the individual receptacles may be of any suitable size that will contain a suitable amount of absorbent material that will sufficiently absorb exudate from a wound site. Generally, the receptacles are sized from about 500 to 5,000 micrometers, preferably about 1000-3000 micrometers in cross-section (independently height and width dimensions). The receptacles in a preferred pattern have a repeat distance defined as the distance from one receptacle to the next receptacle, center axis to center axis, of 500 to 5,000 micrometers, preferably about 1000-4500 micrometers.

While in a preferred embodiment the receptacles have a uniform volume across the transverse directions of the wound dressing, the receptacles may have varying volumes depending upon the location of their openings on the distal surface of the absorbent core. As with the embodiment related to the varying depths of the receptacles, the receptacles located at or near the central portion of the absorbent core may have greater volumetric capacity than the receptacles closer to the border portion of the absorbent core. It follows that the receptacles having varying volumes will likewise contain varying bulk amounts of discrete portions of absorbent material.

The absorbent material used in the dressing of the present invention is preferably comprised of superabsorbent polymeric granulates, flakes or powders that swell on exposure to water and form a hydrated gel (hydrogel) by absorbing large amounts of water. Superabsorbents are defined herein as materials that exhibit the ability to absorb large quantities of liquid, i.e., in

excess of 10 to 15 parts of liquid per part thereof. These superabsorbent materials generally fall into three classes, namely starch graft copolymers, cross-linked carboxymethylcellulose derivatives and modified hydrophilic polyacrylates. Examples of such absorbent polymers are hydrolyzed starch-acrylonitrile graft copolymer, a neutralized starch-acrylic acid graft copolymer, a saponified acrylic acid ester-vinyl acetate copolymer, a hydrolyzed acrylonitrile copolymer or acrylamide copolymer, a modified cross-linked polyvinyl alcohol, a neutralized self-crosslinking polyacrylic acid, a crosslinked polyacrylate salt, carboxylated cellulose, and a neutralized crosslinked isobutylene-maleic anhydride copolymer. Superabsorbent particulate hydrophilic polymers also are described in detail in U.S. Pat. No. 4,102,340. That patent discloses absorbent materials such as cross-linked polyacrylamides. Preferably, the superabsorbent particles used in the dressing of the present invention are preferably composed of cross-linked polyacrylic acid.

Superabsorbent particles are available commercially, for example starch graft polyacrylate hydrogel powders are available from Hoechst-Celanese of Portsmouth, VA. Other superabsorbent particles are marketed under the trademarks SANWET (supplied by Sanyo Kasei Kogyo Kabushiki Kaisha), SUMIKA GEL (supplied by Sumitomo Kagaku Kabushiki Kaisha and which is emulsion polymerized and spherical as opposed to solution polymerized ground particles), and FAVOR (produced by Degussa AG, Dusseldorf, Germany).

The super absorbent particles are preferably in the form of granules or flakes to provide a greater available surface area hydrocolloid. The size of the super absorbent particles is typically within the range of 1 to 1000 micrometers when dry. Preferably, the particle size range of the absorbent particles is 100 to 900 micrometers. The particles which are insoluble in a wound environment have an absorptive capacity greater than 0.5 of water per gram of dry particles.

In another embodiment, the absorbent material may be a hydrophilic gel that swells upon contact with water. The hydrophilic gel generally lacks a cellular or voided internal structure, and is in the form of a solid or semi-solid. Hydrophilic gel may be construed to mean hydrocolloids, hydrogels and combinations thereof as long as the material is physiologically tolerable and clinically acceptable. A description of suitable hydrophilic gels is provided in U.S. 6,566,575 granted to Stickels et al. and such hydrophilic gels are commercially available.

In another embodiment of the wound dressing, the absorbent core may include a plurality of discrete portions of absorbent material enmeshed in the absorbent core. Such discrete portions of absorbent material may be discrete superabsorbent polymeric granulates, flakes or powders that are freely disposed in the absorbent core so that they may migrate within the absorbent core, and preferably towards the distal surface thereof. In yet another embodiment of the wound dressing, the absorbent core may include both absorbent material enmeshed therein and the receptacles containing discrete portions of the absorbent material.

In summary, in each of the absorbent core embodiments discussed thus far, it is notable that the absorption of the fluid at the portion of the absorbent core near or at its proximal portion is minimized, and the absorption of fluid is maximized by the absorption of the absorbent material at or beyond the receptacles. Such a mechanism maximizes the amount of fluid that the dressing can absorb, in combination with the configuration of the backing layer, and further allows longer wear time for the patient since the fluid is not in contact with the skin.

A backing layer may be present in all of the embodiments of the dressing of the present invention. Preferably the backing layer is conformable to animal (inclusive of human) anatomical surfaces, is impermeable to liquid and is vapor permeable. As discussed above, the backing layer, in combination with the

absorbent core, may be constructed to define a reservoir therebetween when the dressing is in an expanded moisture-laden state. While the backing layer does not permit the passage of a liquid or exudate, moisture in the absorbed exudate passes through the backing layer in a vapor form into the atmosphere.

The preferred embodiment for the backing layer is a thin polymeric elastic or flexible film coating providing a bacterial barrier formed from a water vapor permeable pliable elastomer material. The film is continuous in that it has no perforations or pores which extend through the thickness of the film. Films of this type are known and generally are hydrophilic polymeric materials through which water vapor is capable of diffusing.

The backing layer is bonded to the proximal surface of the absorbent core, and in a preferred embodiment, the backing layer is bonded only to the distal surface of the absorbent core and does not penetrate any pores, cells or cavities therein. Generally, the film is 15 to 45 micrometers in thickness, with a preferred thickness of about 30 micrometers. The backing layer may comprise polyurethane, such as a polyurethane film available from InteliCoat Technologies (South Hadley, MA) under product designation INSPIRE, elastomeric polyester, blends of polyurethane and polyester, polyvinyl chloride, and polyether-amide block copolymer. The preferred backing layer for use in the present invention is a polyurethane film since it exhibits a resilient property that allows the film to have good conformability and further has a high degree of stretchability.

It is preferred that the backing layer of the present invention be at least translucent, and more preferably, sufficiently transparent so that the wound site to which the dressing is applied can be viewed through the dressing. It is advantageous to view to evaluate the wound and healing thereof without removal of the dressing to avoid unnecessary handling of the dressing and exposure of the wound to the environment, which reduces the likelihood of contamination.

Suitable continuous conformable backing layers will have a moisture vapor transmission rate (MVTR) of the backing layer alone of 1500 to 14600 g/m<sup>2</sup> /24 hrs, preferably 2500 to 2700 g/m<sup>2</sup> /24 hrs at 38°C. The backing layer thickness is preferably in the range of 10 to 1000 micrometers, more preferably 100 to 500 micrometers. The facing layer of the present invention is preferably a hydrophobic, liquid and moisture impervious layer bonded to the proximal surface of the absorbent core. In a preferred embodiment, the facing layer is a cross-linked silicone elastomer gel, such as, for example, a cross-linked silicone (polydimethyl siloxane gel) manufactured by NuSil Technology (Carpenteria, CA) under product designation MED-6340. The facing layer preferably has a thickness in the range of 0.05 mm to 0.5 mm, and more preferably 0.1 mm. The conformability of the dressing to the wound is somewhat dependent on thickness of the components, such that when the dressing is applied to a body portion, it conforms to the surface even when the surface is moved. When the surface is flexed and then returned to an un-flexed position, the facing layer stretches to accommodate the flexation of the joint but is resilient enough to continue to conform to the surface when the surface is returned to its unflexed condition.

A silicone facing layer has significant advantages over wound dressings that rely on a glue-type adhesive to secure a dressing to a wound. In particular, tacky silicone gels provide a coating which is exceptionally non-adherent to wounds, but which is significantly adherent to surrounding skin. Moreover, such gels are entirely immobile and unaffected by heat or body exudates. This means that dressings according to the invention retain their non-adherent properties even after they have been in place for a substantial period of time, for example, several days.

The silicone gel layer adheres gently to surrounding skin since it is inherently soft to the touch and flows partly into microscopic cavities and cracks in the skin to create a large contact area over the wound site. As a result, less

adhesion force is required to secure the silicone layer over the wound site than in known dressings that include an adhesive layer having glue. Since the silicone layer more fully distributes its adhesion force, the peeling strength thereof does not strip epidermal cells when the dressing is removed from the wound site. Accordingly, the dressing can be reapplied without causing damage to the skin and wound at the wound site. Furthermore, the silicone layer prevents a moisture build-up under such a layer since it is hydrophobic and further since the capillary forces of the absorbent core draw the exudate into the dressing this enables the dressing to be lifted from the skin without causing pain to the wearer of the wound dressing.

The silicones which are used as the facing layer in the dressing of the invention preferably have a Shore A hardness less than 1, and most preferable have no measurable Shore A hardness.

When the silicones are formed by cross-linking a mixture of two or more silicones, the molecular weights of the various components and their degree of substitution by reactive groups may be different. This allows gels having different physical properties to be formed merely by varying the proportions of the components.

The composite facing layer also may include one or more skin treatment agents blended into the silicone elastomer, for example petroleum jelly and aloe vera. In a preferred example, up to 20% by weight of the composite elastic layer, preferably 11.9%, may be petroleum jelly, and up to 3%, preferably 0.1%, may be a secondary skin treatment agent such as aloe vera. It will be understood that different or additional skin treating agents may be utilized, depending upon the skin condition to be treated by the skin treating agent.

In a preferred embodiment, the silicone facing layer is formed as a silicone gel sheet having a predetermined pattern of apertures that are formed prior to the silicone gel sheet being bonded to the absorbent core. Typically, the apertures will have a diameter of 0.05 to 1.0 mm and there are



approximately 50-350 apertures per  $\text{cm}^2$ . While in a preferred embodiment in FIG. 2 the apertures 34 are shown as generally being arranged in a uniform pattern, the facing layer 12 is not limited to this arrangement.

The silicone facing layer may be substantially planar along a proximal surface thereof. Moreover, the silicone facing layer may penetrate or fill surface irregularities of an absorbent core defined as openings, crevices or partial pores located along a surface thereof.

In another embodiment exemplified in FIG. 13, there may be a higher density of apertures 34 in the facing layer 12 corresponding to the central portion 22 of the dressing 10 while there is a lower density or absence of apertures 34 near or along the border portion of the dressing. Alternatively, the facing layer may entirely lack apertures at the border portion of the dressing, and more particularly, a region corresponding to the beveled portion of the absorbent core. This will mitigate fluid absorption at certain areas of the dressing, thereby more effectively directing the exudate absorption in areas that will more efficiently absorb exudate. Furthermore, in yet another embodiment, there is a greater concentration of apertures at or near portions of the absorbent core having the receptacles to thereby enhance exudate uptake towards such receptacles.

Notably, the facing layer is bonded only to the proximal surface of the absorbent core and may penetrate the absorbent core a distance approximately 50% of its thickness. By forming the apertures prior to bonding to the absorbent core, the facing layer does not occlude the cells nor coat the inside walls of the cells of the absorbent core. Accordingly, suitable permeability of the facing layer is preferably obtained by providing the facing layer with preformed apertures located in a suitable array, and accordingly, there is greater control in establishing the transit of fluid through the silicone gel layer.

The thickness of the facing layer may vary across the length thereof. For example, the facing layer may include regions having greater thickness near

the border portion of the wound dressing as opposed to the central portion so as to provide greater strength to the facing layer at such regions thereof having a thicker facing layer.

In yet another embodiment, the facing layer may include at least two different layers having different properties. For example, a softer layer to be worn directly adjacent the wound site may be provided that closely conforms to the wound site while a harder layer may be provided that is interposed between the softer layer and the absorbent core to provide durability and strength to the dressing. The multiple layered or more aptly dual durometer facing layer adopts the principles described in U.S. Patent 6,136,039 granted Oct. 24, 2000 owned by assignee of the invention described herein, the disclosure of which is incorporated herein.

In another embodiment, the facing layer of the present invention may comprise a silicone layer of the type mentioned above that is reinforced with an embedded perforated reinforcement layer. Such a reinforcement layer may include a non-woven, knitted or woven textile material, or a polymeric film such as one made of polyurethane. In this embodiment, the apertures in the silicone layer generally correspond to the perforations of the reinforcement layer.

It will be understood that non-silicone facing layers may be employed in the dressing of the present invention without departing from the scope thereof. Preferably, such facing layers should be soft, flexible, conformable, non-irritating and non-sensitizing. The dressing may include facing layers that comprise a perforated base film constructed of a variety of polymers such as polyurethane, polyethylene, polypropylene, polyamide or polyester material with a pressure-sensitive adhesive. Furthermore, the facing layer may be in the form of moisture vapor permeable films, perforated films, woven-, non-woven or knit webs or scrims. The adhesive may be a microsphere or fibrous adhesive with low trauma properties and have good adhesion to wet skin. It will be understood that the adhesive may be coated on only a portion of the facing layer, for example, the adhesive may be applied only around the border portion

of the dressing with the central portion lacking an adhesive. Preferably, the facing layer should be perforated so as to permit transport of the fluid therethrough to the absorbent core.

The dressing the present invention can include various combinations of ingredients without departing from the scope of the present invention, including, for example, medicaments, soaps, disinfecting and sterilizing agents, odor management, hemostatic agents, proteins, enzymes and nucleic acids. Preferably these agents may be incorporated directly or dispersed in the absorbent core, or dispersed with the absorbent material. Alternatively, these ingredients may be incorporated into the dressing by any suitable means, including an additional layer to the absorbent core that would incorporate such ingredients.

Suitable medicaments, soaps, disinfecting and sterilizing agents, proteins, and enzymes are commercially available. Preferably such medicaments may include antifungal agents, antibacterial agents, angiogenesis promoting agents and other appropriate agents.

As mentioned above in observing FIG. 10, the facing layer 12 may include an adhesive that is provided near or at a peripheral border portion of the facing layer. Preferably, this adhesive is a pressure sensitive silicone such as an adhesive silicone manufactured by NuSil Technology (Carpenteria, CA) under product designation MED-1356 or a very tacky silicone manufactured by NuSil Technology (Carpenteria, CA) under product designation MED-6345. The adhesive silicone may applied to a silicone facing layer after the facing layer is cured such that the adhesive silicone is applied to the facing layer when it is in a partially cured state and then finishes curing when on the facing layer. Alternatively, the adhesive may be an acrylate glue or hot melt glue applied onto the facing layer using conventional methods for applying an adhesive to a substrate.

In a preferred method of the invention, the tacky silicone gel is prepared from a two-component silicone, such as MED-6340 parts A and B produced by

NuSil Technology (Carpenteria, CA). The two parts A and B each include the same base, vinyl-substituted, poly(dimethylsiloxane). In addition, part A includes a platinum catalyst to facilitate a reaction between parts A and B when they are mixed. Part B includes a cross-link, hydride-containing silicone. Both parts A and B are easily mixed, and handled separately, do not react or cure.

The tacky silicone gel is produced by thoroughly mixing parts A and B in a ratio of 1:1, thereby enabling the vinyl-group on the vinyl-substituted silicone to be activated by the catalyst and the hydride containing silicone. This results in cross-linking the silicone so that it will begin to cure. One of the factors that influences the time required for curing is the temperature of the mixed combination of parts A and B. A suitable temperature range is 50-150°C, preferably 100-130°C. Another factor that influences the curing time is the amount of catalyst that is used in the combination of parts A and B, however the catalyst may also undesirably influence the tackiness of the silicone gel. Typically, in the present invention, the curing time of a 0.1 mm thick silicone gel facing layer cured at 100°C is approximately 1 minute, and the silicone gel facing layer is normally transferred to the absorbent core when it is in a partially cured state in a range of 3-12 seconds after parts A and B have been mixed.

It will be understood that the aforementioned steps for preparing the tacky silicone gel are provided for exemplary purposes and the invention is not meant to be limited by such steps. Any suitable steps for preparing a partially cured tacky facing layer may be used while still being within the scope of the present invention.

In the context of the present invention, "partially cured" silicone denotes that the silicone is not completely cured and therefore the silicone is not fully cross-linked. Typically, the parameters for yielding a partially cured silicone layer must be established empirically with respect to the gel mixture and absorbent material used. While the parameters for yielding a "partially cured" silicone layer may vary, the ratio of time required for the silicone gel to become

fully cured may be employed to determine if the silicone layer is partially cured. Specifically, in the present invention, the silicone layer is partially cured between 5-70% of the total time required to cure the silicone gel. It follows that the time interval to apply the facing layer to the absorbent core is between 5-40%; or more preferably 5-20%.

When curing the silicone layer, a catalyzer may be used to speed up the curing time and reduce the tackiness of the silicone gel. A silicone catalyzer is commercially available from NuSil Technology (Carpenteria, CA) under the product designation CAT-50.

A method for securing the backing layer 16 to the absorbent core 14 and formation of the compliant element 26 is preferably performed as illustrated in FIGS. 14-19. In a preferred method, a platen 66, as shown in FIG. 14, may be provided and configured with a profiled surface 70 corresponding to the compliant element 26 and the central 22, intermediate 23 and border portions 24 of a dressing of an embodiment of a wound dressing of the invention. The platen 66 is selectively in communication with a vacuum configured to draw a vacuum along its profiled surface 70 and is heated to a temperature in the range of 150-200°C, preferably 185°C. In a preferred embodiment, the platen 66 includes a groove 68 that extends around the profiled surface 70 that defines the form of the compliant element 26. The platen 66 includes at least one passageway 72 in communication with the groove 68 and a vacuum. The platen 66 may also include a knife edge 74 that extends around the peripheral edge of the profiled surface 72 and a beveled portion 76 near the peripheral edge.

The platen 66 includes at least one recessed portion, such as recessed portions 78, 80, 82 and 84 shown in FIG. 14, that may be disposed about a central portion of the platen 66. The recessed portions 78, 80, 82 and 84 are preferably defined in a step-wise configuration with the central recessed portion 84 being relatively deeper than a first recessed portion 78. The at least one

recessed portion is provided to reduce the pressure exerted at the localized region of the corresponding absorbent core. This results, at least in part, in decreasing the level of adherence of the backing layer at such localized region to the absorbent core. It will be noted that the platen is not limited having recessed portions only in a central portion thereof and may be provided along any portion of the platen where it is desired to have a localized region of less adherence of a backing layer to an absorbent core.

The platen 66 may include a plurality of such passageways 72 that are utilized to communicate the vacuum with a backing layer 16. For example, the platen 66 may include 8 equally spaced passageways about the groove 68 when an absorbent core has a generally rectangular shape. In this example, a passageway may be provided at a location corresponding to intermediate portion of the absorbent core and a passageway may be provided between each corner. Moreover, the platen may include at least one additional passageway 73 that is in communication with compressed air, and such at least one additional passageway may be disposed on the platen corresponding to either the central or border portions.

It will be noted that the platen may be configured according to the shape of the eventual wound dressing and its individual features. For example, the platen may be arranged in a generally circular shape having a groove that is generally circular.

As shown in FIG. 15, the backing layer 16 is placed over the absorbent core 14, and then, as shown in FIG. 16, the platen 66 is positioned against the backing layer 16 and draws the backing layer 16 towards its profiled surface 70 by the vacuum. The platen 66 is continually drawn towards the absorbent core 14 while drawing the backing layer 16 against its profiled surface 70. Of note is that a portion of the backing layer 16 is preferably drawn into the groove 68, thereby forming at least a portion of the compliant element 26. In FIG. 16, the platen 66 is heated at portions of the profiled surface 70 corresponding to the

central, intermediate and border portions 22, 23, 24 of the eventual dressing. The surface of the groove 68 may or may not be heated.

In FIG. 17, the platen 66 positions the backing layer 16 against the absorbent core 14. As can be seen in FIG. 18, the knife portion 74 effectively cuts the absorbent core 14 and backing layer 16, and imparts the beveled portion 28 of the border portion 24 to the dressing 10. Prior to withdrawing the platen 66 from the absorbent core 14, as shown in FIG. 18, the vacuum is removed from the profiled surface 72 and air projected against the backing layer generally at the central portion thereof. As illustrated in FIG. 19, the platen 66 is subsequently removed from the formed absorbent core 14 with the backing layer 16.

In another embodiment, the profiled surface of the platen may be configured so that a central portion thereof corresponding to the central portion of the dressing extends so that it imparts a thickness to the absorbent core that is less than at the area corresponding to the compliant layer and the border portion. This is so that the backing layer will adhere more loosely to the absorbent core at the central portion of the wound dressing. Due to the difference in thickness of the absorbent core, the dressing will have the benefit that the discrete portions of absorbent material will cause the backing layer to detach from the absorbent core more effectively, and will further prevent the backing layer from detaching from the border portion of the dressing before detaching at the central portion of the dressing.

It will be understood that the above described embodiments of the invention may assume a variety of different shapes, sizes and configurations without departing from the scope of the present invention.

It will be understood that the above described embodiments of the invention are illustrative in nature, and that modifications thereof may occur to those skilled in the art. Accordingly, this invention is not to be regarded as

limited to the embodiments disclosed herein, but is to be limited only as defined in the appended claims.



We claim:

1. A wound dressing, comprising:
  - an absorbent core having opposed proximal and distal surfaces, and defining border and central portions along the distal surface thereof; and
  - a liquid impervious, vapor permeable backing layer connected to the absorbent core, said backing layer having at least one compliant element disassociated from the absorbent core.
2. The wound dressing according to claim 1, wherein the at least one compliant element corresponds to an intermediate portion of the absorbent core interposed between the border and central portions thereof.
3. The wound dressing according to claim 2, wherein the absorbent core has a thickness at the central portion thereof that is less than the thickness at the intermediate portion.
4. The wound dressing according to claim 1, wherein the border portion of the absorbent core includes a beveled portion near a peripheral edge thereof.
5. The wound dressing according to claim 1, wherein a thickness of the absorbent core progressively decreases from an outer section of the intermediate portion to the border portion thereof.
6. The wound dressing according to claim 5, wherein the thickness of the absorbent core is at a minimum along a peripheral edge of the border portion.
7. The wound dressing according to claim 1, wherein the backing layer is permanently secured to the absorbent core along the border portion thereof.
8. The wound dressing according to claim 7, wherein the backing layer is sealed along the peripheral edges of the absorbent core.

9. The wound dressing according to claim 1, wherein the border portion of the absorbent core includes at least one beveled portion, said backing layer permanently secured to the absorbent core along the border portion thereof.

10. The wound dressing according to claim 1, wherein said backing layer is attached to the central portion of the absorbent core when said wound dressing is substantially devoid of moisture, said backing layer is configured to disassociate from the central portion of the absorbent core when the wound dressing has absorbed a quantity of moisture.

11. The wound dressing according to claim 1, wherein the compliant element includes at least one ridge concentric to the periphery of the absorbent core extending substantially outwardly relative to the distal surface of the absorbent core.

12. The wound dressing according to claim 1, wherein the compliant element is defined as a portion of the backing layer extending generally coplanar with the distal surface of the absorbent core when the wound dressing is substantially devoid of moisture.

13. The wound dressing according to claim 1, further comprising a perforated, skin adherent facing layer secured to the proximal surface of the absorbent core.

14. The wound dressing according to claim 13, wherein the facing layer is a discrete layer of silicone gel.

15. The wound dressing according to claim 1, wherein the absorbent core is selected from the group consisting of polymeric foam, woven material, and non-woven material.

16. The wound dressing according to claim 1, wherein the backing layer is selected from the group consisting of latex rubber, silicone film, polyurethane film, and polyethylene film.

17. The wound dressing according to claim 1, wherein the absorbent core contains discrete portions of at least one absorbent material.

18. The wound dressing according to claim 17, wherein the discrete portions of absorbent material are enmeshed in the absorbent core.

19. The wound dressing according to claim 18, wherein the absorbent material is selected from the group consisting of hydrocolloids, hydrogels, and hydrophilic polymers.

20. The wound dressing according to claim 17, wherein the discrete portions of absorbent material are disposed in receptacles formed along the distal surface of the absorbent core.

21. A method for making a wound dressing including an absorbent core having proximal and distal surfaces, a liquid impervious, vapor permeable backing layer extending over the distal surface of the absorbent core that includes a portion defining a compliant element disassociated and outwardly extending from the distal surface of the absorbent core, said method comprising the steps of:

securing a border portion of the backing layer to a border portion of the absorbent core located near the periphery thereof;

connecting a central portion of the backing layer to a central portion of the absorbent core; and

forming the compliant element by drawing said compliant element away from the absorbent core.

22. The method according to claim 21, wherein the compliant element is drawn from the absorbent core with a vacuum as the border and central portions of the backing layer are connected to the absorbent core.

23. The method according to claim 22, further comprising the step of removing the vacuum from the backing layer.

24. The method according to claim 23, further comprising the step of injecting compressed air against the backing layer after the compliant element has been formed.

25. The method according to claim 21, wherein a platen configured with a predetermined profile corresponding to the compliant element and the border and central portions of the backing layer is employed to secure the backing layer to the absorbent core, the platen including at least one groove defining the form of the compliant element of the backing layer and selectively in communication with a vacuum.

26. The method according to claim 25, further comprising the steps of:  
drawing the backing layer against the platen prior to bonding the border and central portions thereof to the absorbent core by pulling the area of the backing layer corresponding to the compliant element into the at least one groove with a vacuum in communication therewith;

applying the platen with the backing layer carried thereon against the absorbent core, said platen being heated at a suitable temperature to secure the border portion of the backing layer to the absorbent core; and

removing the vacuum from the backing layer after the border portion of the backing layer is secured to the absorbent core.

27. The method according to claim 25, wherein compressed air is exerted against the central portion of the backing layer to separate the platen therefrom.

28. The method according to claim 25, wherein the platen includes a tapered profile corresponding to an end portion of the border portion adjacent the periphery of the wound dressing, said profile imparting a tapered edge to the wound dressing.

29. The method according to claim 25, wherein the platen includes at least one recessed portion defined along the profile thereof.

30. The method according to claim 29, wherein the at least one recessed portion is defined about a central axis of the platen.

31. The method according to claim 30, wherein the platen includes at least two concentric recessed portions.

32. The method according to claim 21, further comprising the step of sealing the peripheral edges of the absorbent core with the backing layer.

33. The method according to claim 25, wherein the at least one groove is connected to at least one passageway in communication with compressed air.

34. The method according to claim 33, further comprising the step of exerting compressed air via the at least one passageway against the compliant element to form two concentric ridges.

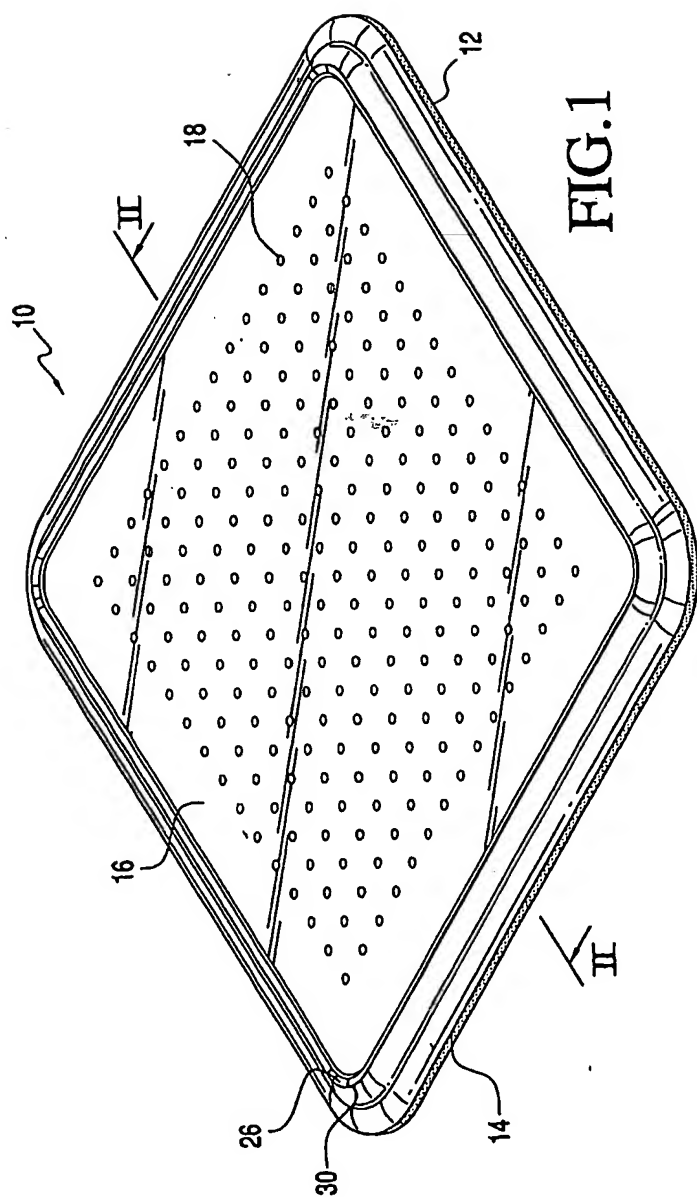


FIG. 1

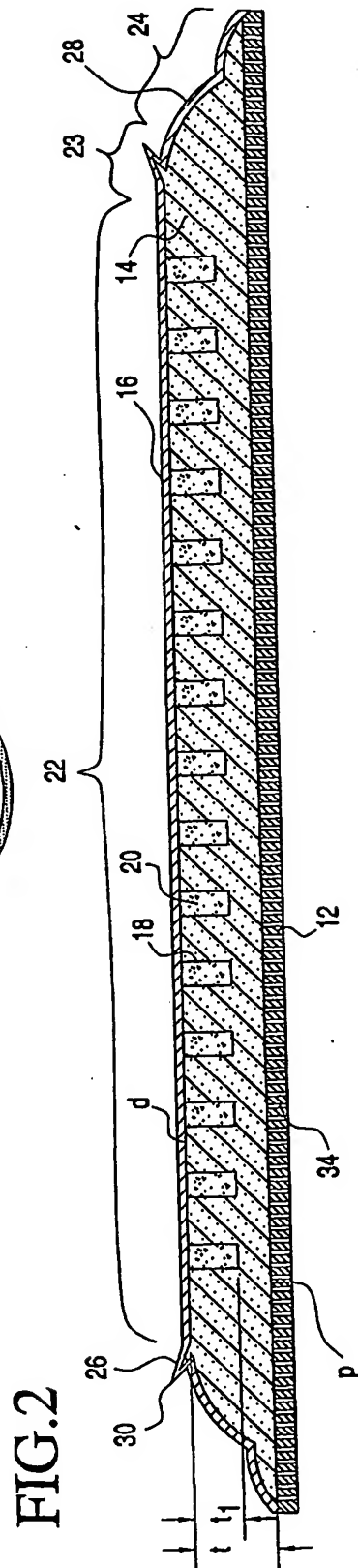


FIG. 2

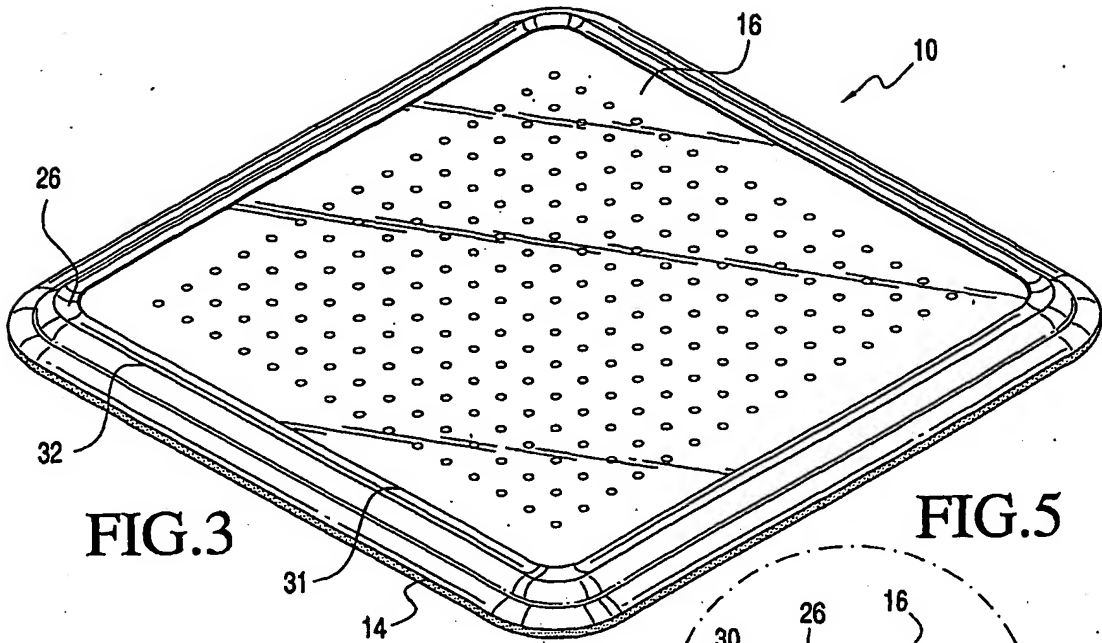


FIG. 3

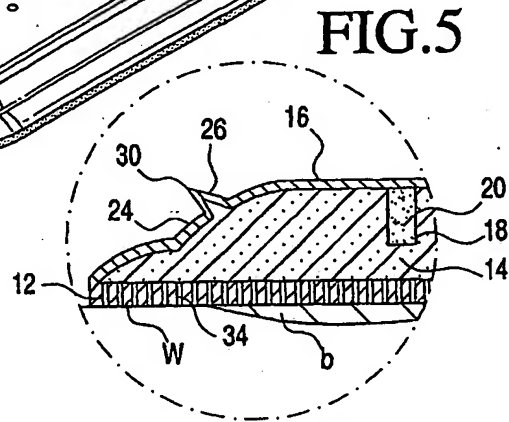


FIG. 5

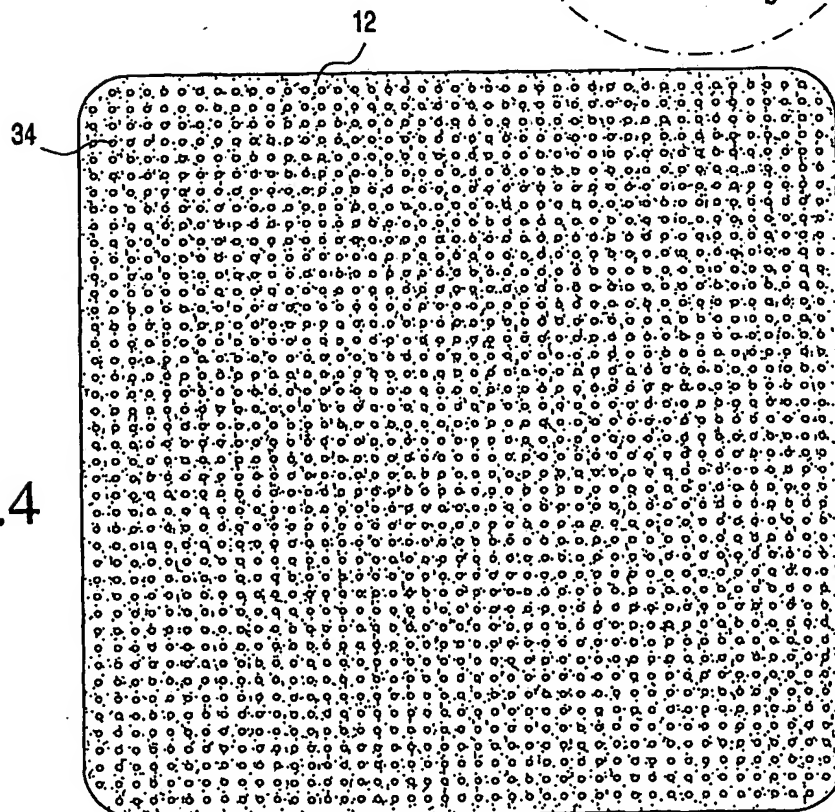
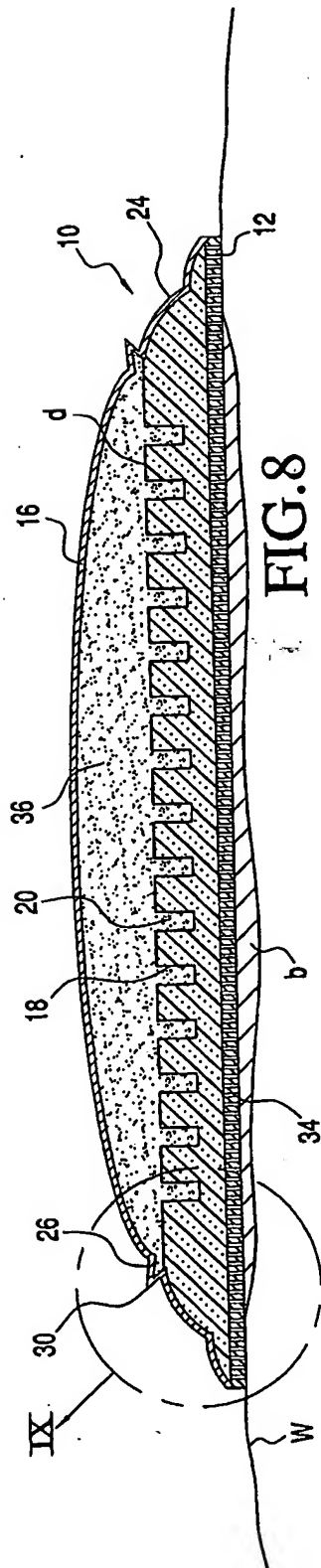
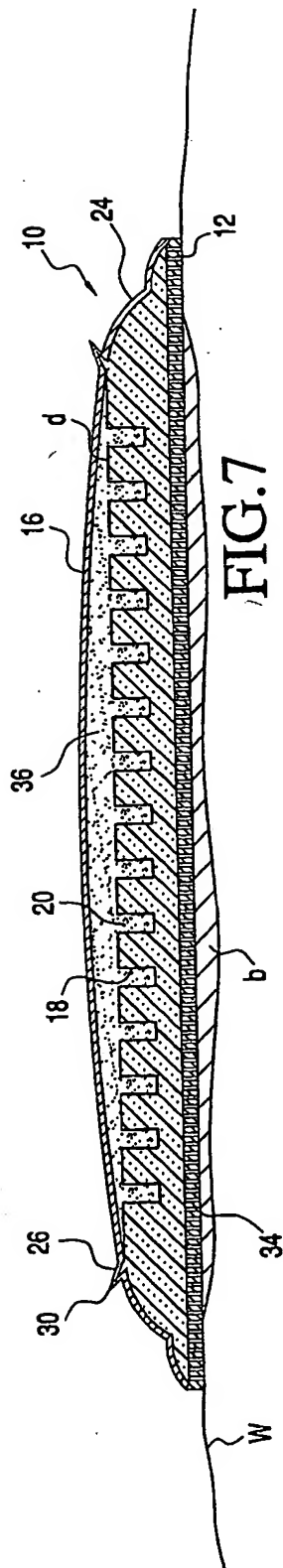
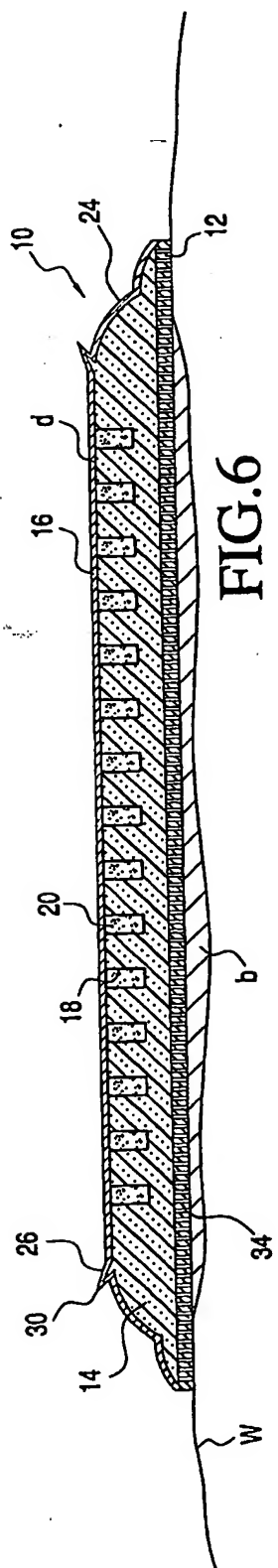


FIG. 4





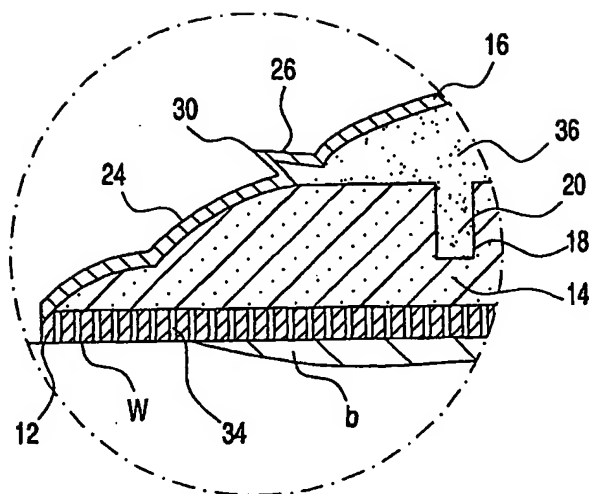


FIG.9

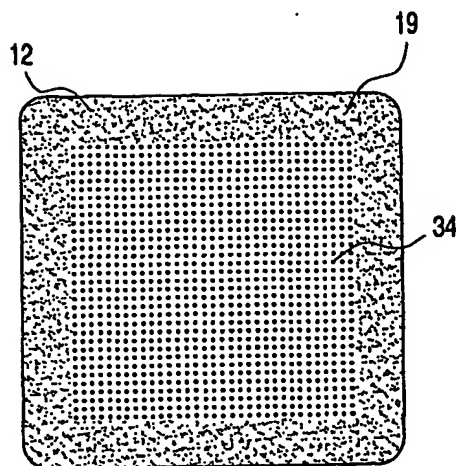


FIG.10

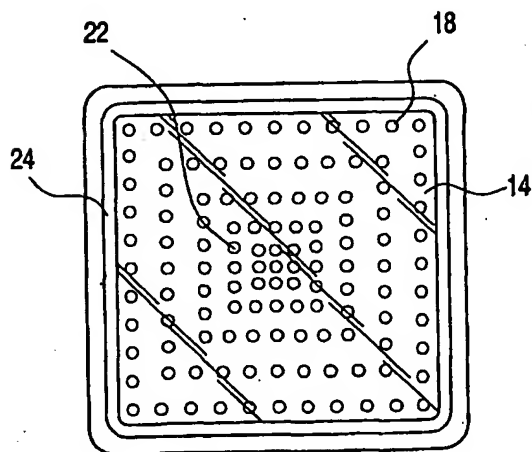


FIG.11

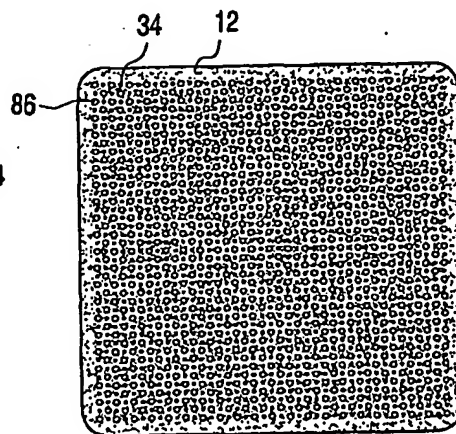


FIG.12

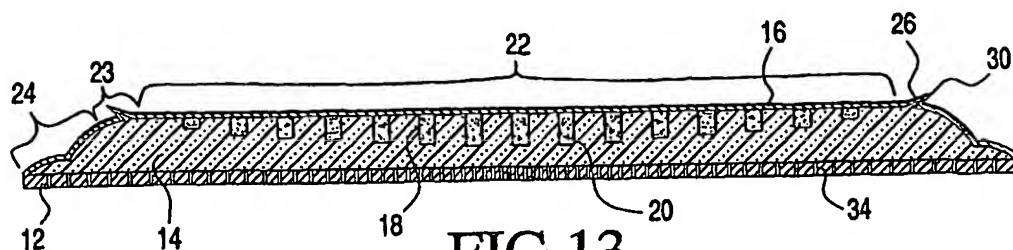


FIG.13

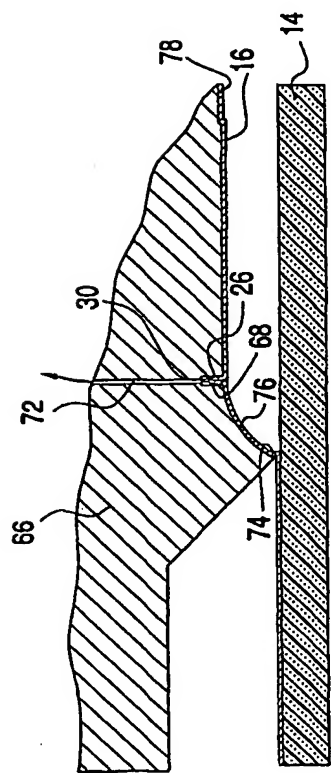
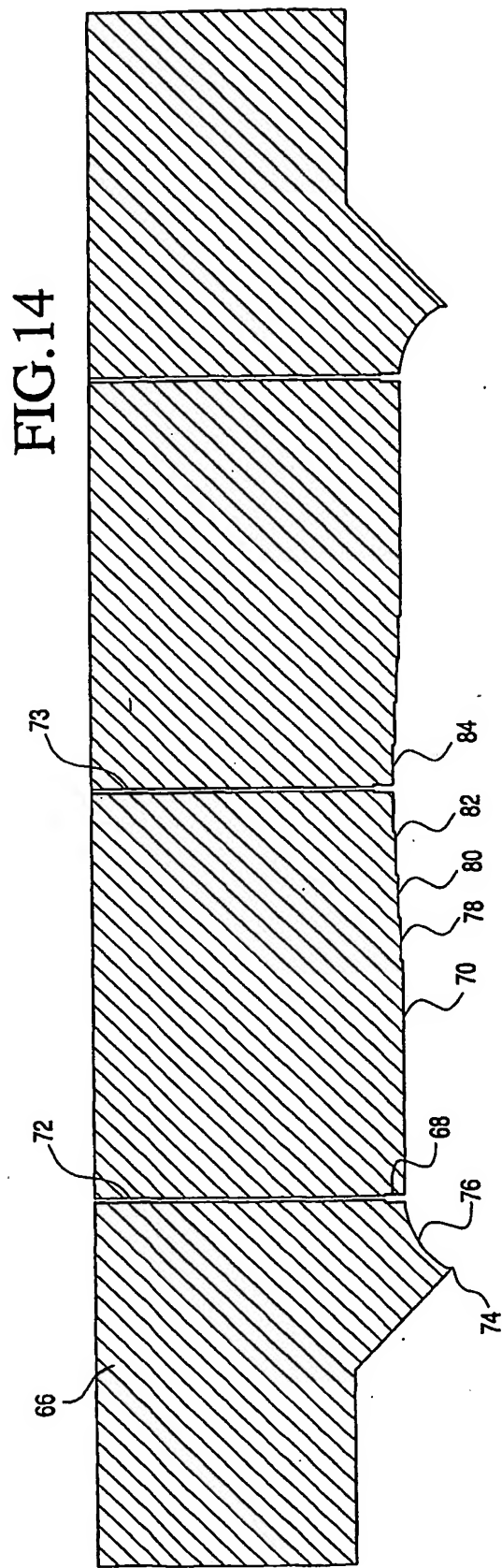


FIG.15

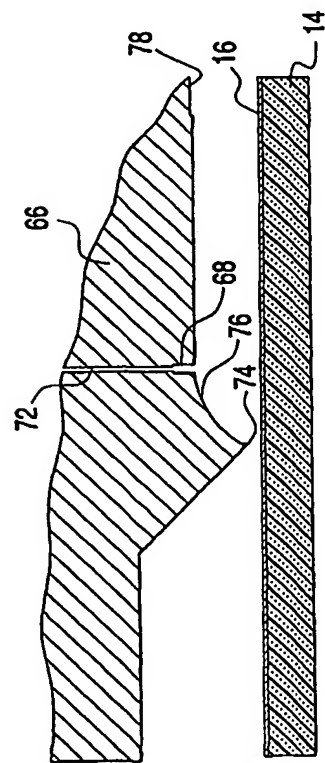
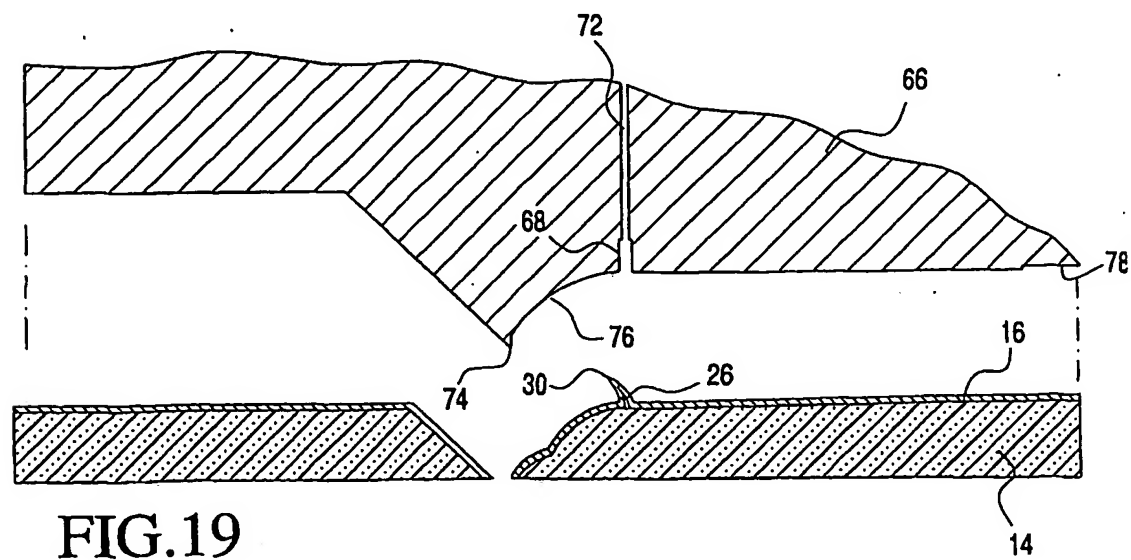
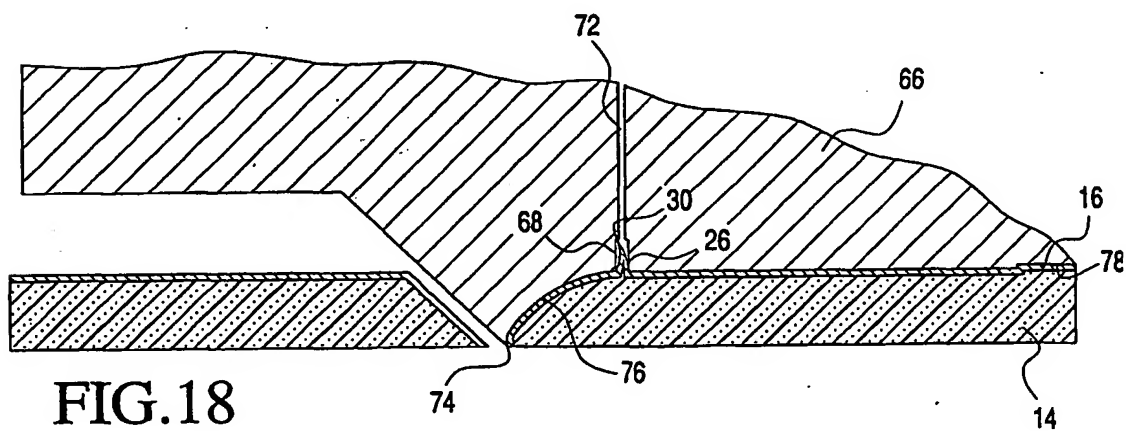
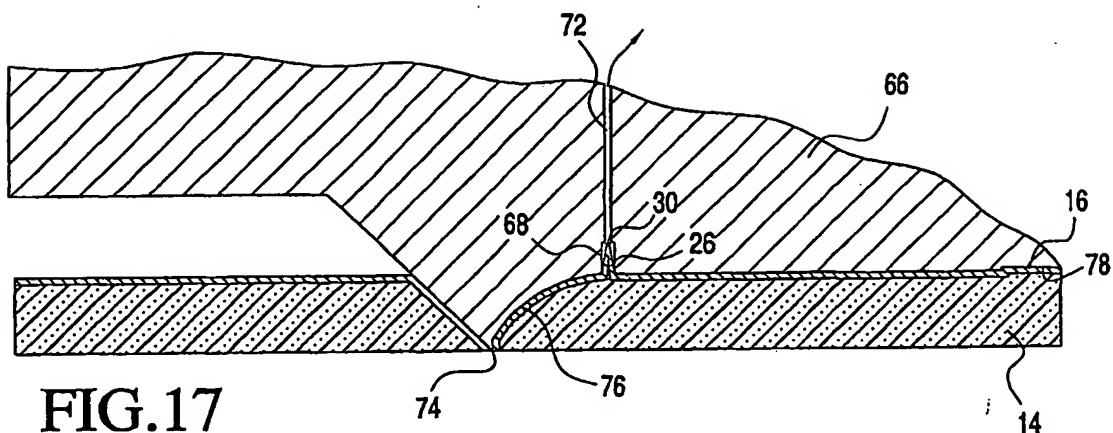


FIG.16



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/37075

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 13/00

US CL : 602/45

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 602/45

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A — P	US 6,653,520 B1 (MOUTON) 25 November 2003 (25.11.2003), See entire document.	1-34
A — P	US 6,566,575 B1 (STICKELS et al) 20 May 2003 (20.05.2003), See entire document.	1-34
A	US 6,333,093 B1 (BURRELL et al) 25 December 2001 (25.12.2001), See entire document.	1-34



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

17 March 2004 (17.03.2004)

Date of mailing of the international search report

22 APR 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Glenn Richman

Telephone No. 703 308 0858